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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.		
10/592,995	05/31/2007	Roy Deodutta	21085.0063U2	5907		
23859	7590	01/26/2009	EXAMINER			
Ballard Spahr Andrews & Ingersoll, LLP SUITE 1000 999 PEACHTREE STREET ATLANTA, GA 30309-3915				BASKAR, PADMAVATHI		
ART UNIT		PAPER NUMBER				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/592,995	DEODUTTA, ROY
	<b>Examiner</b>	<b>Art Unit</b>
	Padma V. Baskar	1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 9/15/06.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) \_\_\_\_\_ is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) 1-41 are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
- Certified copies of the priority documents have been received.
  - Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application
- 6) Other: \_\_\_\_\_.

### **Election/Restrictions**

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Group I, claims 1-3 drawn to polypeptide SEQ.ID.NO:1.

Group II, drawn to a polynucleotide, SEQ.ID.NO:2, vector and a host cell.

Group III, claims 10-15, drawn to an antibody.

Group IV, claims 16-18 and 19 and 22 drawn to a method for detecting expression of a tumor suppressor gene or whether a subject at risk for developing cancer in a subject comprising analyzing a sample from the subject for expression of a SKCG-1 gene SEQ ID NO: 2, wherein reduced expression of SKCG-1 gene indicates that the subject has or is at risk.

Further restriction to one tumor cell i.e., breast cancer or renal cancer or ovarian cancer is required.

Group V, claims 20 and 22 drawn to a method whether a subject at risk for developing cancer in a subject comprising analyzing the methylation status of a SKCG-1 gene in a sample.

Further restriction to one tumor cell i.e., breast cancer or renal cancer or ovarian cancer is required

Group VI, claims 21 and 22 drawn to a method for determining whether a subject has or is at risk for developing cancer comprising: detecting the presence or absence in the SKCG-1 gene of said subject a genetic polymorphism comprising the nucleotide sequence set forth in SEQ ID NO: 3, with one or more point mutations.

Further restriction to one tumor cell i.e., breast cancer or renal cancer or ovarian cancer is required

Group VII, claims 23-31/32-40 and 41 drawn to a method suppressing growth of a tumor cell, comprising introducing into the tumor cell an expression vector comprising a polynucleotide encoding a polypeptide having the amino acid sequence shown in SEQ

ID NO: 1, wherein expression of the polypeptide in the tumor cell, suppresses growth of the tumor cell.

Further restriction to one tumor cell i.e., breast carcinoma cell or a renal carcinoma cell or an ovarian carcinoma cell is required.

Please note: claim 31 is a duplicate claim of claim 30.

Please note: claims 32-40 are duplicate claims of 23-31.

2. The inventions listed as Groups I-VII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The special technical feature of Group I is considered to be a polypeptide, which is made up of amino acids nucleic acids.

The special technical feature of Group II is considered to be a polynucleotide that shares no common structure, property and function with Group II since polynucleotide contains nucleic acids and does not share the same or a corresponding technical feature with Group I.

The special technical feature of Group III considered to be antibody that shares no common structure, property and function from Inventions I-II since it has an inherent affinity, avidity, and specificity that DNA or a simple protein is not capable of expressing and do not require each other for their practice.

Since the special technical feature of the Group I invention is not present in the Group II-III claims, and the special technical features of the Group II-III inventions are not present in the Group I claims, unity of invention is lacking.

The technical feature linking Groups IV-VII is considered to be methods utilizing products SEQ.ID.NO:2 or 3 or SEQ.ID.NO:1 that results in different outcome.

Pursuant to 37 C.F.R. § 1.475 (d), the ISA/US considers that where multiple products, processes and methods are claimed, the main invention shall consist of the first invention of the category first mentioned in the claims and the first recited invention of each of the other categories related thereto. Accordingly the main invention (Group 1) comprises polypeptide acids, which is the first product (please note: there is no method utilizing the first product polypeptide).

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Further pursuant to 37 C.F.R. § 1.475 (d), the ISA/US considers that any feature which the subsequently recited products and methods share with the main invention does not constitute a special technical feature within the meaning of PCT Rule 13.2 and that each of such products and methods accordingly defines a separate invention. Therefore, the groups of inventions above do not constitute a special technical feature within the meaning of PCT Rule 13.2 and that each of such products and methods accordingly defines a separate invention.

3. In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted. The reply must also identify the claims readable on the elected invention, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

***Conclusion***

4. Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform to the notice published in the Official Gazette, 1096 OG 30, November 156, 191. The Right Fax number is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PMR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PMR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Padma Baskar Ph.D., whose telephone number is ((571) 272-0853. A

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message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 6.30 a.m. to 4.00 p.m. except First Friday of each bi-week.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on 571) 272-0956.

Respectfully,  
/Padma V Baskar/  
Examiner, Art Unit 1645

/Robert B Mondesi/  
Supervisory Patent Examiner, Art Unit 1645